REMARKS

Applicants wish to thank the Examiner for examination of the present application. Claims 1, 20, 21, 27, 28, 29, 40, 42, 43, 45, 50, and 52-54 have been amended. Claims 2, 18, 30, 31, 39, 41, 47, 48, 55 and 56 are cancelled. Claims 3-11, 13, 14, 19, 22-26 are original. Claims 12, 15-17, 32-38, 44, 46, 49 and 51 are previously presented. With the claim amendments below, claims 1, 3-17, 19-29, 32-38, 40, 42-46 and 49-54 are now pending in this application. No new matter has been added.

35 U.S.C. §112

Claim 50 is rejected under 35 U.S.C. §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claim was rendered indefinite for lack of clarity of the claim language. Applicants have amended the claim to correct the grammar and therefore believe this rejection is now moot.

35 U.S.C. §102

Claims 1, 3-5, 8, 11-14, 16, 17, 19-26, 28-29, 34-48, 40, 42-46 and 49-56 stand rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,712,856 to Carignan, (Carignan).

Carignan fails to teach or suggest each and every element of Applicants claims. For example, each of pending independent claims 1, 27, and 28 requires in some form, among other things, an implant having a bone-facing implant surface that includes, at least in part, a planar surface to abut a corresponding bone cut surface of a patient's condyle.

Although the office action maintains that Carignan discloses a device having such a planar surface to accommodate a corresponding bone cut, that is not correct. Carignan fails to teach or suggest an implant having such a planar surface. Instead, Carignan describes a trochlear resurfacing device that not only does not employ a bone cut, but expressly teaches away from such a cut. In particular, Carignan describes a device having a "bottom" trochlear surface that is matched to an adjacent trochlear surface of a femur.

The office action bases its conclusion that Carignan discloses a planar surface on the statement in Carignan that there is "almost no removal of the original bone." (See col. 7, lines 2-

4.) Based on that statement, the office action concludes that the original bone may be cut to some degree, and, implicitly therefore, that the cut is planar. This assumption is not correct. As an initial matter, the entire section of Carignan clearly teaches that the goal is to avoid any bone removal at all:

> "In the past, replacement of a diseased knee joint required surgical modification of the surface of the femur so as to allow a close "fit" of the prosthetic device within the new joint. This required extensive removal or carving of the cartilage and bone surfaces of the head of the femur in order to "match" with the back surface of a standardized prosthetic device. ***With the present invention***, there is almost no removal of original bone and therefore, ***no loss of requisite anatomical structures***. Insertion of the replacement device requires minimal removal of existing anatomic structures, if at all. Therefore, ***the intent is to remove only the diseased portion (the natural cartilage) of the patient's knee joint*** prior to installing the replacement device."

(col. 6, lines 63-67, col. 7, lines 1-8 (emphasis added)). The statement cited in the office action, "there is almost no removal of original bone," cannot be reasonably interpreted to mean a bone cut is made when the preceding passage notes that such carving of bones to "'match' [] the back [planar] surface of a standardized prosthetic device" is the exact problem identified in the specification and the expressly stated "intent" of the invention is to avoid such bone removal and to instead remove only diseased cartilage. Those express teachings of the specification coupled with the fact that no embodiment of the Carignan specification shows such any such planar surface, and the conclusion of the office action cannot be sustained.

Furthermore, whatever bone loss there may be in the course of a surgical procedure cannot be assumed to be a planar bone cut absent some express disclosure to that effect. Given the context of the specification, any bone loss more logically would be attributed to minor bone loss such as during drilling of peg holes (for pegs that are expressly disclosed), or attributable to other incidental and/or unintended bone loss such as from scrapping or burring during the intended removal of diseased cartilage. Thus, given both the context and express disclosure of the specification, it cannot be assumed that one skilled in the art would assume the meaning proffered in the office action over this more likely contextual meaning of the phrase, or some other meaning more consistent with the express statements of the specification.

Taken in context, it is clear that the device of Carignan, in which almost no original bone is removed, no requisite anatomical structure is lost, no planar cut is explicitly disclosed and only cartilage is intended to be removed, does not disclose the features of the invention of the present application. Instead, Carignan discloses an improvement over the past devices that required surgical modification of the surface of the femur ("extensive removal or carving of the cartilage and bone surfaces of the head of the femur in order to "match" with the back surface of a standardized prosthetic device"). The device of Carignan is said to be an improvement over past devices since "the intent is to remove only the diseased portion (the natural cartilage) of the patient's knee joint prior to installing the replacement device" instead of the "extensive removal or carving of the cartilage and bone surface of the head of the femur." In other words, the Carignan device does not require removal of or carving (i.e. cutting) the surface of the femur. The office action actually acknowledges this feature of Carignan when it states that "the implant [of Carignan] is designed to rebuild a cartilage defect in a patient and to match the ***uncut*** femoral bone of a patient with a custom fit." (Office Action paragraph 5 (emphasis added)).

The office action does note in the response to arguments section that the device of Carignan has a bone-facing surface that "is fully capable of abutting a bone cut surface." While this may strictly be true, it still does not result in a disclosure of all the elements of the claims. First, the "customized" bone-facing surface of Carignan would not function if placed against a planar bone cut. Second, even if the "customized" bone-facing surface of Carignan can be placed – in a dysfunctional manner – against a planar bone cut, the Carignan device still does not have, teach or suggest a ***planar*** bone-facing surface as claimed.

Therefore, since Carignan does not teach or suggest a condylar bone-facing implant surface comprising a planar surface to abut a bone cut surface of the patient's condyle and actually teaches away from a device that requires cutting the patient's femur, independent claims 1, 27 and 28 cannot be anticipated by Carignan. Claims 3-5, 8, 11-14, 16, 17, 19-26, 29, 34-38, 40, 42-46 and 49-56 depend from independent claims 1, 27 and 28 and are not anticipated by Carignan for at least the same reasons.

Claims 20 and 21 have been amended to include structural limitations of the claimed device.

Claim 51 depends from claim 1. Therefore, the term "portion" as used in claim 51 refers to the element and section of the device referred to in claim 1, namely "a condylar **portion** having (i) a condylar bone-facing implant surface configured to oppose at least a portion of a femoral condyle and (ii) a condylar articular implant surface configured to articulate with at least a portion of a tibial surface."

35 U.S.C. §103

Claims 6, 7, 9, 10, 32, and 33 stand rejected under 35 U.S.C. §103 over Carignan in view of U.S. Patent Application Publication 2003/0060882 to Fell (Fell), and claims 15 and 27 stand rejected under 35 U.S.C. §103 over Carignan in view of U.S. Patent Application Publication 2004/016730 to Rolston (Rolston).

As stated above, Carignan does not anticipate applicant's claims and neither Fell nor Rolston cure the deficiencies in Carignan. Fell describes a unicompartmental interpositional spacer for placement between the femur and tibia without any bone resection or mechanical fixation. Rolston describes a bicompartmental arthroplasty device having standard, off-the-shelf interior and exterior surfaces. Neither describes, for example, a patient-specific implant, including a patient specific device having an articular surface that replicates the curvature of the uncut articular surface of the patient's condyle, as required by Applicant's claims.

Thus, Applicants' claims cannot be obvious in view of any combination of Carignan, Fell, and/or Rolston.

Applicants reserve all other arguments with respect to the Examiner's rejections, including any argument that Applicants may have invented the claimed subject matter earlier than the priority date of any one or more of Carignan, Fell, and Rolston.

Conclusion

It is submitted that the application is in condition for allowance and Applicants respectfully request issuance of a notice of allowance. It is believed that a three month extension of time is required. Applicants respectfully petition for any required extension. Authorization is hereby given to charge deposit account number 19-4972. If any additional fees are required for the timely consideration of this application, please charge deposit account number 19-4972.

Applicants request that the undersigned, Alexander J. Smolenski, Jr., be contacted if it will assist further examination of this application.

Respectfully submitted,

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